

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

WYETH,	)	
	)	
	)	
Plaintiff,	)	
	)	Civil Action No.: 06-222 JJF
v.	)	
	)	
IMPAX LABORATORIES, INC.,	)	
	)	
Defendant.	)	
_____	)	

**DEFENDANT'S BRIEF IN SUPPORT OF MOTION FOR  
PROTECTIVE ORDER TO GOVERN THE  
PRODUCTION OF DOCUMENTS IN RESPONSE TO SUBPOENA**

RICHARD K. HERRMANN (I.D. No. 405)  
MARY B. MATTERER (I.D. No. 2696)  
MORRIS JAMES LLP  
500 Delaware Avenue, 15<sup>th</sup> Floor  
Wilmington, DE 19801  
Telephone: (302) 888-6800  
mmatterer@morrisjames.com

M. PATRICIA THAYER (*pro hac vice*)  
JOHN M. BENASSI (*pro hac vice*)  
JESSICA R. WOLFF (*pro hac vice*)  
DANIEL N. KASSABIAN (*pro hac vice*)  
SAMUEL F. ERNST (*pro hac vice*)  
HELLER EHRMAN LLP  
4350 La Jolla Village Drive, 7th Floor  
San Diego, CA 92101  
Telephone: (858) 450-8400  
Facsimile: (858) 450-8499

*Attorneys for Defendant IMPAX LABORATORIES, Inc.*

March 20, 2007

## TABLE OF CONTENTS

	Page
I. NATURE AND STAGE OF PROCEEDINGS .....	1
II. FACTUAL BACKGROUND .....	3
A. Wyeth sues Impax for infringement of its patents claiming methods for administering extended release venlafaxine formulations. ....	3
B. Alza sues Wyeth for infringement of its patent claiming a method for administering extended release venlafaxine formulations. ....	3
C. Wyeth refuses to respond to Impax's discovery requests regarding the Alza formulations. ....	4
D. Impax serves a document subpoena on Alza. ....	4
E. Wyeth refuses to stipulate to the protective order negotiated by Impax and Alza.....	5
III. ARGUMENT .....	7
IV. CONCLUSION .....	11

## TABLE OF AUTHORITIES

	Page
<b>CASES</b>	
<i>Pearson v. Miller</i> , 211 F.3d 57 (3d Cir. 2000) .....	7
<b>STATUTES</b>	
35 U.S.C. § 101 .....	3
35 U.S.C. § 271(e)(2)(A) .....	2
<b>RULES</b>	
Fed. R. Civ. P. 26(c).....	7
Fed. R. Civ. P. 26(c)(7) .....	7

## **I. NATURE AND STAGE OF PROCEEDINGS**

Defendant Impax Laboratories, Inc. (“Impax”) brings this motion seeking the entry of a protective order to govern the production of documents produced by third party Alza Corporation (“Alza”) in response to Impax’s subpoena. Impax and Alza have come to an agreement as to the terms of this protective order but Plaintiff Wyeth (“Wyeth”) has refused to stipulate to the entry of the order unless Alza agrees that Wyeth may use Alza’s highly confidential documents produced in response to the subpoena in litigation between Wyeth and Alza pending in the Eastern District of Texas. Because Wyeth has no legitimate interest in the level of protection given the highly confidential documents Alza produces in response to Impax’s subpoena, and because Wyeth’s refusal to stipulate to this order appears to be the latest attempt by Wyeth to block all discovery by Impax regarding the Alza prior art formulations, Impax brings this motion asking the Court to enter the protective order Impax and Alza negotiated.

Wyeth brought this action for patent-infringement to prevent Impax from selling a generic version of Wyeth’s product EFFEXOR® XR, which is a formulation of the anti-depressant medication venlafaxine hydrochloride. Third Party Alza has, in turn, sued Wyeth in the United States District Court for the Eastern District of Texas, claiming that Wyeth’s EFFEXOR® XR product infringes Alza’s patent on a method for administering an extended release venlafaxine formulation. In the instant litigation, Impax contends that the Alza patent is invalidating prior art.

In the course of discovery, Impax has learned that Wyeth and Alza had a joint-development agreement in the 1990s to develop extended release venlafaxine compounds using Alza’s technology. Documents produced by Wyeth indicate that some of the formulations developed by Alza are likely additional invalidating prior art to the patents asserted by Wyeth in the instant litigation.

Accordingly, Impax has attempted to take discovery regarding the Wyeth-Alza collaboration, but has met with roadblocks erected by Wyeth at every turn. Wyeth refused to respond to Impax's interrogatory regarding the Alza collaboration, forcing Impax to obtain an order from the Court compelling Wyeth to answer the interrogatory. (Oral Order of March 2, 2007). Wyeth has moreover refused to produce documents in response to five Impax document requests regarding the Alza formulations. Wyeth's consistent argument, rejected by the Court in granting Impax's recent motion to compel, is that it need not respond to discovery regarding the Alza prior art formulations because information regarding the Alza formulations are irrelevant to this lawsuit, even though Impax contends that the prior art Alza formulations are invalidating prior art.

Impax has therefore attempted to discover documents directly from Alza regarding the Alza formulations by the vehicle of a document subpoena. Alza has agreed to produce documents, but quite naturally requests a protective order to protect the highly confidential documents it produces in response to the subpoena. One of the protections Impax and Alza have negotiated for that protective order is a provision to the effect that any documents Alza produces in response to this subpoena may not be used by Wyeth against Alza in the Texas litigation. Wyeth refuses to stipulate to a protective order containing this provision, arguing that it should be able to use Alza's highly confidential documents produced here in the Alza litigation, even though Wyeth has consistently contended that the Alza litigation is irrelevant to this lawsuit. Because the continued delay in the production of Alza documents is prejudicing Impax's defense of this lawsuit, Impax brings the instant motion for the entry of the protective order Alza and Impax negotiated, so that the production of documents in response to the subpoena may commence.

## II. FACTUAL BACKGROUND

### A. Wyeth sues Impax for infringement of its patents claiming methods for administering extended release venlafaxine formulations.

Wyeth initiated this action against Impax on April 5, 2006 alleging patent infringement under 35 U.S.C. § 271(e)(2)(A) by reason of Impax's submission to the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 78-057.<sup>1</sup> D.I. 1. Impax filed its Answer and Counterclaims on April 25, 2006, denying infringement and asserting a defense and counterclaim that the patents-in-suit are invalid pursuant to 35 U.S.C. §§ 101 *et seq.* D.I. 7. Impax filed its First Amended Complaint on August 10, 2006 asserting an additional defense and counterclaim that the patents-in-suit are unenforceable for inequitable conduct. D.I. 33.

### B. Alza sues Wyeth for infringement of its patent claiming a method for administering extended release venlafaxine formulations.

Wyeth itself has been sued by Alza in the Eastern District of Texas. *See* Declaration of Mary B. Matterer in Support of Impax's Motion to Compel ("Matterer Decl."), Ex. 1. In that litigation, Alza claims that Wyeth's EFFEXOR® XR product infringes Alza's U.S. Patent No. 6,440,457 ("the Alza Patent").

Impax has also discovered documents indicating that during the 1990s Wyeth and Alza had entered into an agreement to jointly develop formulations of venlafaxine using Alza's extended release technology. Matterer Decl., Ex. 2 at WYETH 012-000150.

Impax has further discovered documents indicating that in the course of this collaboration, Alza made extended release formulations that may well invalidate the patents-in-suit. *See, e.g.,* Matterer Decl., Exs. 3, 4.

---

<sup>1</sup> The patents-in-suit are U.S. Patent No. 6,274,171 ("171 patent"), U.S. Patent No. 6,403,120 ("120 patent"), and U.S. Patent No. 6,419,958 ("958 patent").

**C. Wyeth refuses to respond to Impax's discovery requests regarding the Alza formulations.**

In light of these discoveries, Impax posed interrogatory number 35 to Wyeth regarding its collaboration with Alza and the Alza extended release venlafaxine formulations. Wyeth refused to respond to this interrogatory, forcing Impax to file a motion to compel, which the Court recently granted. (Oral Order of March 2, 2007).

Wyeth has also refused to produce documents in response to five document requests by Impax regarding the Alza formulations. Matterer Decl., Ex. 5 at Responses Nos. 106-110.

**D. Impax serves a document subpoena on Alza.**

On November 21, 2006, Impax served a document subpoena on Alza, in order to discover information regarding the Alza formulations directly from Alza. Matterer Decl., Ex. 6.

On December 21, 2006, Alza served objections and responses to Impax's subpoena. Matterer Decl., Ex. 7. Alza agreed to produce documents in response to the subpoena, but stated that it would only produce documents "once an appropriate protective order is in place." *See, e.g., id.*, Ex. 7 at 6. Accordingly, Alza and Impax began the process of negotiating the protective order that is the subject of this motion – to govern the production of documents by Alza in response to the subpoena. Matterer Decl., Ex. 8 ("Protective Order").

At that time, Impax and Wyeth were still negotiating a general protective order to govern the production of documents by the parties to this litigation. Alza reviewed the protective order the parties were negotiating but requested that a separate protective order be entered to govern the production of documents in response to the subpoena. The reason for this was that Alza is involved in litigation against Wyeth in the Eastern District of Texas. Alza wanted to ensure that Wyeth would not use documents produced by Alza in this litigation against Alza in the Texas litigation, and that attorneys working on this

litigation would not work on the Texas litigation equipped with knowledge obtained from accessing highly confidential Alza documents produced in response to the subpoena.

Accordingly, Alza proposed a provision in the Protective Order providing that:

In no event shall any attorney involved in *Alza Corp. v Wyeth & Wyeth Pharmaceuticals, Inc.*, C.A. No. 9:06-CV-156-RHC, pending in the United States District Court for the Eastern District of Texas, Lufkin Division (or any related proceeding) (hereinafter “The Texas Litigation”), or in Reexamination Control Number 90/008,142, pending in the United States Patent and Trademark Office (or any related proceeding) (hereinafter “The Reexamination”) have access to documents and material marked "Highly Confidential" by Alza.

*Id.*, Ex. 8 ¶ 4(a).

This provision affects none of the attorneys who have appeared on behalf of Wyeth in this lawsuit. This is because in this lawsuit Wyeth is represented by the law firms of Finnegan Henderson Farabow Garrett & Dunner LLP (“Finnegan”) and Morris, Nichols, Arsht & Tunnell LLP (“Morris Nichols”). In the Texas litigation, Wyeth is represented by different attorneys at different law firms: the law firms of Beck, Redden & Secrets, L.L.P. (“Beck, Redden”) and Wilmer Cutler Pickering Hale and Dorr LLP (“Wilmer Cutler”). Matterer Decl., Ex. 9 at 7.

**E. Wyeth refuses to stipulate to the protective order negotiated by Impax and Alza.**

Nonetheless, after Impax and Alza agreed to a form of protective order to govern the production of documents in response to the subpoena, Wyeth refused to stipulate to entry of the order based on an objection to this provision in the protective order.

Impax sent the protective order to Wyeth on February 23, 2007, signed by counsel for Impax and Alza. Matterer Decl., Ex. 10. Impax requested that Wyeth “[p]lease advise us if Wyeth will agree to sign this protective order so that we may request the Court to enter it as a stipulation.” *Id.*, Ex. 10.

On March 5, 2007, Wyeth wrote to Impax asking why a separate protective order was necessary regarding the production of documents by Alza. *Id.*, Ex. 11.



Impax responded on March 6, 2007 explaining that

Alza reviewed the protective order that Impax and Wyeth had been negotiating for some months and that was recently entered by the Court, but Alza was dissatisfied with that form of order to govern the production of Alza documents in response to our subpoena. The protective order that we negotiated with Alza provides some additional protections for Alza confidential information (in particular, with regard to paragraph 4) to ensure that documents Alza produces in this litigation are not used for the purpose of any other litigation or proceeding. We feel this is entirely appropriate.

*Id.*, Ex. 12 at 1.

Nonetheless, on March 7, 2007, Wyeth wrote to counsel for Alza objecting to the form of the protective order and asking that this precise provision be deleted:

As written the draft is not acceptable. We suggest the following changes for Alza's consideration: delete the last sentence of paragraph 4(a); delete the phrase ' , provided that no person identified in this subparagraph shall have any involvement in the Texas Litigation or the Reexamination'

*Id.*, Ex. 13 at 1.

Impax wrote to Wyeth on March 8, 2007 stating again that Alza had a legitimate concern and that Wyeth had no legitimate interest in the scope of protection to be afforded Alza highly confidential documents:

Alza was particularly concerned that Wyeth counsel in this litigation should not work on the Alza/Wyeth litigation because it is impossible for a person to compartmentalize his mind between cases. Please explain why Wyeth has any legitimate interest in broadening the disclosure of highly confidential Alza documents produced in response to this subpoena.

*Id.*, Ex. 14 at 1.

Wyeth did not respond to Impax's letter by articulating any legitimate concern it had in the level of protection afforded Alza's highly confidential documents. Rather, on March 12, Wyeth wrote back to Impax merely to complain that "Impax elected to negotiate a separate protective order with Alza without including us in those negotiations." *Id.*, Ex. 15.

On March 13, 2007 Impax wrote to Wyeth that

Impax did not include Wyeth in the negotiations with Alza surrounding the protections to govern Alza documents produced in response to our subpoena because we could conceive of no legitimate interest Wyeth could have in the protections surrounding these documents. These are not Wyeth's documents. These documents are not being produced in response to Wyeth's subpoena.

*Id.*, Ex. 16. Impax further stated that if Wyeth would not stipulate to the entry of the protective order Impax and Alza had negotiated, Impax would move for the entry of the order.

Counsel for Wyeth have told Impax that they are negotiating language for an alternative protective order that Wyeth will agree to and that they may have reached an agreement in principle, but have not yet confirmed that they have signed any such alternative protective order. Because Impax must have this matter heard at the April discovery hearing in order to receive these documents in time to use them at upcoming depositions, Impax cannot await the uncertain outcome of these negotiations. Impax therefore brings the instant motion for entry of the protective order Impax and Alza negotiated.

### **III. ARGUMENT**

The Court is empowered to enter a protective order "for good cause shown" upon a motion by any party or by a person from whom discovery is sought. Fed. R. Civ. P. 26(c). Among the protective orders this Court may issue is an order providing "that a trade secret or other confidential research, development, or commercial information not be disclosed or be disclosed only in a designated way." Fed. R. Civ. P. 26(c)(7). Here Impax seeks the entry of a protective order providing that Alza highly confidential documents be disclosed only to persons who will not use them for purposes other than the instant litigation and in particular, not in the litigation between Alza and Wyeth pending in the Eastern District of Texas.

To obtain entry of the protective order, Impax must show “good cause,” which is defined as a “showing of injury, with specificity.” *Pearson v. Miller*, 211 F.3d 57, 72 (3d Cir. 2000). In determining whether good cause is shown, “the flexibility of Rule 26 also allows the court to take into account the particular needs of the parties at the present stage of litigation.” *Id.* at 73.

Here, there is good cause for the entry of the protective order to prevent the mounting prejudice to Impax in its defense of this lawsuit occasioned by Wyeth’s consistent efforts to block all discovery of the Alza prior art formulations. Wyeth has objected to and has refused to produce *any* documents in response to five Impax document requests regarding the Alza formulations under the improper objection that this information is irrelevant. Matterer Decl., Ex. 5 at 30-34 (Responses to Requests for Production Nos. 106, 107, 108, 109, 110). As Impax has now repeatedly explained to Wyeth, information regarding the Alza formulations is relevant to Impax’s claim that these formulations invalidate the patents-in-suit.

Nonetheless Wyeth also refused to respond to Impax’s Interrogatory No. 35 regarding the Alza formulations under the same improper irrelevancy objection. Impax was forced to move to compel a response to this Interrogatory, which the Court recently granted. Oral Order of March 2, 2007.

Now Wyeth interposes a frivolous objection to a protective order to govern the production of documents by a *third party* in response to a subpoena propounded by Impax, not by Wyeth. Wyeth has no legitimate interest in the level of protection afforded Alza’s highly confidential documents. The only interest it has is an improper interest in using those documents for purposes other than this litigation. This interest is illegitimate for two important reasons:

First, the general protective order Wyeth stipulated to that was entered by the Court in this case on February 7, 2007 acknowledges that it would be improper for Wyeth to use highly confidential Alza documents produced in this litigation for any purpose other than

the prosecution of this litigation. That order provides that

Confidential information and Highly Confidential information shall not be used for any research, development, manufacture, patent filing or prosecution, financial purpose, commercial purpose, marketing purpose, business purpose, regulatory purpose, Citizen's Petitions, lawsuits against the FDA, *any other litigation* or other competitive purpose except as required by law.

D.I.84 ¶ 2 (emphasis added). In light of this provision Wyeth stipulated to, Wyeth cannot assert a legitimate interest in the ability to use highly confidential documents produced by Alza for the purposes of the Texas litigation.

Second, the further protection that Alza seeks ensuring that attorneys who view highly confidential Alza documents do not work on the Texas litigation against Alza will have no effect on Wyeth's ability to prosecute either the Texas litigation or this lawsuit. That is because Wyeth is represented by wholly different attorneys working at wholly different law firms in each of these two litigations. In this law suit, Wyeth is represented by Finnegan and by Morris, Nichols. In the Texas litigation, Wyeth is represented by the law firms of Beck, Redden and Wilmer Cutler. Matterer Decl., Ex. 9 at 7. In this lawsuit alone, at least six attorneys have entered appearances on behalf of Wyeth thus far. None of these attorneys have entered appearances in the Texas litigation, in which at least six different attorneys have appeared on behalf of Wyeth. Surely Wyeth will incur no prejudice if the six attorneys representing it in this litigation either do not assist in the Texas litigation or, if Wyeth wishes one of them to assist in the Texas litigation, if that particular attorney does not view the highly confidential Alza documents produced in response to Impax's subpoena.

Third, Wyeth cannot claim that it requires the ability to use the highly confidential Alza documents in the Texas litigation to avoid the duplicative expense and inconvenience of discovering those documents again in the Texas litigation. Such an argument would be contrary to the letter and spirit of the protective order in this case, which prohibits the use

of confidential documents produced in discovery to advance other litigation. D.I. 84 ¶ 2. Moreover, it is Impax, not Wyeth, who has incurred the expense and trouble of subpoenaing documents from Alza in this litigation. There will be no duplication of effort on Wyeth's part if it seeks to discover the same documents in the Texas litigation.

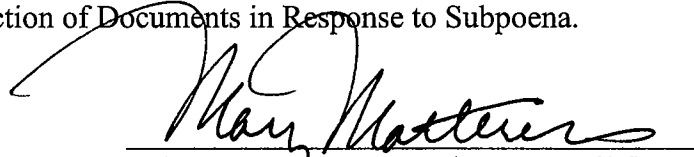
Fourth, the Texas litigation is currently stayed pending the PTO reexamination of the patent-in-suit in that litigation. Matterer Decl., Ex. 17. As such, Wyeth simply has no need for the Alza highly confidential documents produced in this law suit for the purposes of the Texas litigation at any time in the foreseeable future.

Wyeth's only possible interest in refusing to stipulate to the protective order is a desire to further delay or prevent Impax's discovery of information regarding the Alza formulations, to Impax's great prejudice. Impax urgently requires this discovery in light of the pace of discovery in this law suit. Wyeth has already deposed one Impax employee and noticed depositions for two additional Impax employees in the last week. Impax is meanwhile deprived of the ability to review the Alza documents in time to take depositions of Wyeth regarding the Alza-Wyeth collaboration.

The Court should not brook Wyeth's tactics to block Impax's discovery of the invalidating Alza prior art formulations. Impax and Alza have agreed to the form of protective order to govern the Alza documents and Wyeth has no conceivable interest in the protections afforded these documents other than to hinder Impax's ability to defend this law suit.

#### IV. CONCLUSION

For the foregoing reasons, the Court should grant Impax's Motion for Protective Order to Govern the Production of Documents in Response to Subpoena.



MARY B. MATTERER (I.D. No. 2696)  
RICHARD K. HERRMANN (I.D. No. 405)  
MORRIS JAMES LLP  
500 Delaware Ave., 15th Floor  
Wilmington, DE 19801  
Telephone: (302) 888-6800  
mmatterer@morrisjames.com

M. PATRICIA THAYER (*pro hac vice*)  
JOHN M. BENASSI (*pro hac vice*)  
JESSICA R. WOLFF (*pro hac vice*)  
DANIEL KASSABIAN (*pro hac vice*)  
SAMUEL F. ERNST (*pro hac vice*)  
HELLER EHRMAN LLP  
4350 La Jolla Village Drive, 7th Floor  
San Diego, CA 92101  
Telephone: (858) 450-8400  
Facsimile: (858) 450-8499

Attorneys for IMPAX LABORATORIES, INC.

Dated: March 20, 2007